|  |  |  |
| --- | --- | --- |
| Patient Information **Patient Name** S1  **DOB**  **Sex** Unknown  **MRN** 18513 | Reference Information **Ordering Physician** Dr. M. Abcedek  **Order Date** 02/01/2023  **Contact/Recipient**  **Additional** | Sample Information **Specimen Site**  **Collection Date** 02/02/2023  **Received Date** 02/06/2023  **Accession #** 38154 |

## **About the Test**

Golden Labs utilizes a Next Generation Sequencing (NGS) based assay of cancer-related genes to detect relevant genomic alterations that provide therapeutic guidance, disease diagnostic evidence or prognostic indication. See Methods and Limitations.

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Results Summary**  **Negative Findings**  No pathogenic single nucleotide variants, indels, copy number changes, or structural variations found for:  | **EGFR** | **ALK** | **ROS1** |  **Genomic Signatures**  The following genomic signature(s) were analyzed for this sample:  TMB: High | 12.5 mut/Mb  MSI: High | 35.9 % unstable MSI loci  HRD: Positive | 43 Genomic Instability Score   |  |  | | --- | --- | | **Genomic Finding** | **Number of Findings Detected** | | Genomic Findings with Clinical Evidence | 10 | | Genomic Findings with Prognostic/Diagnostic Evidence | 2 | | Variants with Uncertain Clinical Significance | 0 | | Germline Alterations | 1 | |

# **Genomic Findings with Evidence of Clinical Significance**

## **Genomic Findings with Clinical Evidence**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Genomic Finding | FDA-Approved Therapies  in Patient’s Tumor Type | Therapies of Potential Significance | Resistance | Potential Clinical Trials |
| ALK Negative Finding (NF) EGFR Negative Finding (NF) ROS1 Negative Finding (NF) | Cemiplimab-rwlc, Durvalumab + Tremelimumab, Nivolumab + Ipilimumab (1A) | None | None | No |
| ALK Negative Finding (NF) EGFR Negative Finding (NF) | None | Durvalumab + Tremelimumab, Nivolumab + Ipilimumab (1A) | None | No |
| Unspecified | Afatinib, Atezolizumab, Bevacizumab, Durvalumab, Necitumumab, Nivolumab, Ramucirumab (1A) | None | None | No |
| Unspecified | Atezolizumab, Durvalumab, Nivolumab (1A) | None | None | Yes, see clinical trials section |
| BRAF V600E | Dabrafenib, Dabrafenib + Trametinib, Vemurafenib (1A) | Dabrafenib + Trametinib, Encorafenib + Binimetinib (2C) Vemurafenib + Rituximab (2C) Encorafenib + Cetuximab, Encorafenib + Panitumumab (2C) Vemurafenib + Cobimetinib (2C) Trametinib, Vemurafenib + Cobimetinib, Vemurafenib + Cobimetinib + Atezolizumab (2C) | Dabrafenib + Trametinib (2D) Cetuximab, Panitumumab, Trametinib (2C) | Yes, see clinical trials section |
| PIK3CA Amplification | None | Alpelisib + Fulvestrant, Everolimus + Exemestane, Fulvestrant (2C) Alpelisib + Fulvestrant, Everolimus + Exemestane, Fulvestrant (2C) | None | No |
| TMB High | Pembrolizumab (1A) | None | None | No |
| MSI High | Pembrolizumab (1A) | Dostarlimab-gxly (2C) Avelumab (2C) Dostarlimab-gxly (2C) Avelumab (2C) | None | No |
| HRD Positive | None | Olaparib, Talazoparib (2C) Niraparib, Olaparib, Olaparib + Bevacizumab, Rucaparib (2C) Olaparib (2C) Olaparib, Rucaparib (2C) Olaparib, Talazoparib (2C) Niraparib, Olaparib, Olaparib + Bevacizumab, Rucaparib (2C) Olaparib (2C) Olaparib, Rucaparib (2C) | None | No |
| ERBB2 Amplification | Ado-trastuzumab emtansine, Fam-trastuzumab deruxtecan-nxki (1A) | Trastuzumab, Trastuzumab + Pembrolizumab (2C) Fam-trastuzumab deruxtecan, Trastuzumab, Trastuzumab + Pembrolizumab (2C) Lapatinib, Margetuximab-cmkb, Neratinib, Trastuzumab, Trastuzumab + Lapatinib, Trastuzumab + Pertuzumab, Trastuzumab + Tucatinib (2C) | Afatinib, Trastuzumab (1A) | Yes, see clinical trials section |
| ABL1 Fusion with BCR | None | Asciminib, Bosutinib, Dasatinib, Imatinib, Nilotinib, Ponatinib (2C) | None | No |

## **Genomic Findings with Prognostic or Diagnostic Evidence**

|  |  |  |  |
| --- | --- | --- | --- |
| Gene | Description | Location | Evidence |
| *BRAF* | Val600Glu | Exon 15 | Prognostic Tier II - Level C Diagnostic Tier I - Level A |
| *ERBB2* | Amplification | Amplification | Prognostic Tier I - Level B |

## **Somatic Variants with Clinical Evidence**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Genomic Finding | VAF | Impact | Location | Classification | Evidence |
| *BRAF*  Val600Glu | 6.18% | Activating Mutation | Exon 15 | Oncogenic | Drug Sensitivity Tier I - Level A Drug Resistance Tier II - Level C |

## **Structural Variations with Clinical Evidence**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Primary Gene | Location | Reads | WT Reads | State | Evidence |
| *ABL1* | BCR::ABL1 | - | - | Transcript fusion | Drug Sensitivity Tier II - Level C |

## **Copy Number Variations with Clinical Evidence**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Primary Gene | Overlapping Genes | State | ISCN | Impact | Evidence |
| *PIK3CA* | PIK3CA, KCNMB3 | Duplication | 3q26.32 (3:178866145-178957881)x3 | Activating Mutation | Drug Sensitivity Tier II - Level C |
| *ERBB2* | ERBB2, MIR4728, MIEN1 | Duplication | 17q12 (17:37856317-37884911)x0 | Activating Mutation | Drug Sensitivity Tier I - Level A Drug Resistance Tier I - Level A |

## **Genomic Signatures with Clinical Evidence**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Genomic Finding | State | Location | Impact | Evidence |
| TMB High | 12.5 mut/Mb | Genomic Signature | Unknown | Drug Sensitivity Tier I - Level A |
| MSI High | 35.9 % unstable MSI loci | Genomic Signature | Unknown | Drug Sensitivity Tier I - Level A |
| HRD Positive | 43 Genomic Instability Score | Genomic Signature | Unknown | Drug Sensitivity Tier II - Level C |

## **Negative Findings with Clinical Evidence**

|  |  |
| --- | --- |
| Primary Gene | Description |
| EGFR | Negative Finding |
| ALK | Negative Finding |
| ROS1 | Negative Finding |

## **Other Reported Biomarkers**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| |  |  |  | | --- | --- | --- | | Gene | Type | Description | | *MYCL* | Amplification | Amplification | | *TFRC* | Amplification | Amplification | | |  |  |  | | --- | --- | --- | | Gene | Type | Description | | *PIK3CB* | Amplification | Amplification | | *ERCC2* | Amplification | Amplification | |

# **Variants with Uncertain Clinical Significance**

## **Germline Alterations Detected**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Gene | Type | Description | Genotype | Disease Risk | Classification |
| *RAF1* | Missense Variant | Ser257Leu | Heterozygous | Autosomal Dominant | Pathogenic |

**Relevant Clinical Trials**

## **Clinical Trials Summary**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Genomic Finding | Type | NCT ID | Drugs | Phase |
| BRAF V600E | Mutation | NCT04302025 | Atezolizumab, Vemurafenib, Cobimetinib | II |
| Unspecified | Disease | NCT05091567  NCT03782207  NCT03811002 | Atezolizumab  Atezolizumab  Atezolizumab, Cisplatin | III    II/III |
| ERBB2 Amplification | CNV | NCT04579380 | trastuzumab | II |

**Methods and Limitations**

**METHODOLOGY**

The individual’s DNA was extracted and fragmented, with fragments from the coding regions of the select gene panel targeted for amplification and sequencing. Reads from the sequence output were aligned to the human reference genome (GRCh37) using the Burrows-Wheeler Aligner (BWA). Variants to the reference were called using the Genomic Analysis Tool Kit (GATK). The variants were annotated and filtered using the Golden Helix VarSeq analysis workflow implementing the ACMG guidelines for interpretation of sequence variants. This includes comparison against the gnomAD population catalog of variants in 123,136 exomes, the 1000 Genomes Project Consortium’s publication of 2,500 genomes, the NCBI ClinVar database of clinical assertions on variant’s pathogenicity and multiple lines of computational evidence on conservation and functional impact. This test has not been cleared or approved by the U.S. Food and Drug Administration (FDA). The FDA has determined that such clearance or approval is not necessary.

**VARIANT ASSESSMENT PROCESS**

The following databases and algorithms are used to annotate and evaluate the impact of the variant in the context of human disease: 1000 genomes, gnomAD, ClinVar, OMIM, dbSNP, NCIB RefSeq Genes, ExAC Gene Constraints, VS-SIFT, VS-PolyPhen2, PhyloP, GERP++, GeneSplicer, MaxEntScan, NNSplice, PWM Splice Predictor. Analysis was reported using HGVS nomenclature ([www.hgvs.org/mutnomen](http://www.hgvs.org/mutnomen)) as implemented by the VarSeq transcript annotation algorithm. The reported transcript matches that used most frequently by the clinical labs submitting to ClinVar.

**LIMITATIONS**

It should be noted that this test is restricted to a limited number of genes and does not include all intronic and non-coding regions. This report only includes variants that meet a level of evidence threshold for cause or contribute to disease. Certain classes of genomic variants are also not covered using the NGS testing technology, including triplet repeat expansions, copy number alterations, translocations, gene fusions, or other complex structural rearrangements. More evidence for disease association of genes and causal pathogenic variants are discovered every year, and it is recommended that genetic variants are re-interpreted with updated software and annotations periodically.

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